

### **REMARKS**

Claims 1 to 18, 67 and 71 to 85 are currently pending. In view of the following remarks, reconsideration and withdrawal of the rejection is respectfully requested.

#### **I. TELEPHONE COMMUNICATION WITH THE EXAMINER**

The undersigned and the applicants contacted the Examiner by telephone on March 24, 2006 to discuss the status of the application and to explain to the Examiner certain of applicants' positions on some of the technical and legal issues raised by the office action. The positions presented during the telephone communication are essentially the same as those presented herein.

#### **II. THE PENDING CLAIMS ARE PATENTABLE**

##### **A. REJECTION UNDER 35 U.S.C. § 102(b)**

The Examiner has rejected claims 1 – 18, 67 and 71 - 85 as being anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 3,635,856 to Kaneko et al. (hereinafter "Kaneko") "as affirmed by" the Mitsubishi-Kagaku internet publication entitled "Introduction of Sugar Esters" (hereinafter "Mitsubishi").

(Action, p. 2-3). This rejection is respectfully traversed for at least three reasons:

(1) the combination of Kaneko with Mitsubishi is improper; (2) even if it were proper to combine them, the combination of Kaneko and Mitsubishi does not teach or suggest the invention as now claimed; and (3) the invention as presently

claimed produces unexpected results.

In order to help the Examiner understand applicants' reasoning behind the three reasons mentioned above, it will be helpful to review some of the background leading to the present invention and the technical advances that the present invention provides. As mentioned in the present specification (p. 7, ll.24 et seq.), the requirements of a shapeable composition, particularly a composition adapted for PVC extrusion, can be demanding. For example, the combining or blending aspect of the shaping process frequently causes heating within a composition, which in turn causes individual particles of the composition to soften and fuse, creating a substantially homogeneous mass. When such heating and blending is performed under known standard testing conditions, the period of blending required to reach the fusion point is referred to as the "fusion time." With further continued blending, it is expected that the composition would begin to degrade and cross-link, increasing the viscosity of the composition and hence the blending torque. Since such cross-linking is generally not desired, the ability of the mass to be blended without cross-linking is a measure of the stability of the composition.

The elapsed time between the fusion point and the beginning of a measurable rise in viscosity due to cross-linking is referred to as the "stability time." In general, with all other features being substantially equal, an extrudable composition which has a relatively long stability time will have significant processing advantages, and potentially significant advantages in the finished product. One aspect of the present invention, relates to the discovery that

certain combinations of compounds which form the shapeable mass of the present invention have surprising and unexpected performance in terms of, for example, stability time. As explained in detail hereinafter (see Section E below), neither the combination of compounds nor such an advantageous property is suggested in any of the prior art of record.

### **B) The Combination of Kaneko and Mitsubishi is Improper**

The present rejection is respectfully traversed as Kaneko and Mitsubishi can not be combined for anticipatory purposes. In general "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). However, an additional reference may be cited in an anticipatory rejection to prove that the primary reference contains an enabled disclosure, or to explain the meaning of a term used in the primary reference, or to show that a characteristic not disclosed in the primary reference is inherent. MPEP § 2131.01. Mitsubishi as cited by the Examiner satisfies none of these requirements.

As an initial matter, applicants repeat here what has been expressly stated previously during the prosecution of this application: highly and fully substituted sucrose ester **compounds** were not invented by the present inventors. (See also the Supplemental IDS submitted herewith). These compounds were known to exist at the time the present invention was made. Importantly, the present

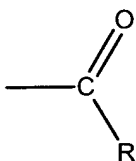
claims do not simply define such compounds. Rather, the present claims are directed to **processes for extruding a resin-containing composition**. One limitation in the claimed process requires the use **in the extrusion process** of saccharide ester in which **at least about 50%** by weight of the saccharide ester compounds of Formula I are fully substituted esters. As explained hereinafter, applicants' invention as now claimed resides, at least in part, in the recognition that beneficial and unexpected results can be achieved in **extrusion processes** when such compounds are used as claimed.

### **C) The Cited Patents Do Not Anticipate or Suggest The Claimed Invention**

Even if it were proper to combine Kaneko and Mitsubishi, applicants respectfully submit that there is nothing in either Kaneko or Mitsubishi that teaches or even suggests a process which uses a composition in accordance with the pending claims. The Examiner cites Mitsubishi to "affirm" that the structure of the saccharide ester disclosed in Kaneko "is substantially identical" to that required by Formula I. (Action, p.3). The Examiner does not explain how the Mitsubishi publication in 2002 is relevant to the Kaneko publication from 1979, or why or how the disclosure in Mitsubishi should be interpreted as disclosing some inherent characteristic of the material in Kaneko. The disclosure of Mitsubishi does **not** prove that Kaneko contains an enabled disclosure, or explain the meaning of a term used in Kaneko, or demonstrate an inherent characteristic of

Kaneko. Accordingly, the citation of Mitsubishi in combination with Kaneko in an anticipatory rejection is improper.

The Examiner contends that the present claims are anticipated by Kaneko as the A substituents of Formula (I) are not limited to esters of Structure (I); thus, according to the Examiner, the ester-substituted sugars of Kaneko are alleged to be "substantially identical" to those of Formula (I). (Action, p.3-4). However, the present claims are directed to a process which uses a composition **in which at least 50%** of the compounds of Formula (I) are limited to those octa-substituted with the ester of Structure (I). In other words, the present claims require that at least about one of every two ester substituted sugar compounds, by weight, present in the composition must be fully substituted with ester in accordance with structure I, which is reproduced below:



There is nothing in Kaneko which suggests a composition that contains **any** octa-substituted esters, much less a composition having such a high concentration of such esters, as required by the present claims.

Applicants respectfully submit that when considered as a whole, as is required by the applicable case law, the Kaneko patent teaches compositions comprising predominately sucrose mono-esters and sucrose di-esters. More specifically, the Kaneko patent states at column 4, lines 46-50:

The sucrose alkyl esters may be those having an hydrophile-lipophile balance value (HLB) below 6.0 and include mono-esters or diesters of fatty acids... and mixtures thereof.

The above statement makes it clear to a person skilled in the art that Kaneko teaches use **only** of mono- and diesters, "and mixtures thereof." There's simply no suggestion anywhere that the mixtures could or should include sucrose esters having a higher degree of substitution.

To the extent the Examiner has interpreted the statement in Kaneko relating to a material having an HLB below 6.0 as teaching a composition in accordance with the present invention, such a position is technically flawed. In the first instance, applicants respectfully submit that the measurement of an HLB value, even when such a measurement is conducted pursuant to known and well-established procedures, cannot be considered as a complete and accurate characterization of the degree of substitution of the many compounds that may be included in a given composition. In support of this position, applicants submit herewith the Second (unsigned) Declaration of inventor Durrenberger. An executed version will be filed within the next several days. As explained in this declaration, it is not possible to determine from any non-zero HLB value alone the concentrations of the various compounds which may be present in a mixture of compounds having varying degrees of ester substitution. Thus, it is certainly possible, and in fact perhaps likely depending on the circumstances, that two compositions having similar HLB values will have substantially different distributions of compounds, particularly as it relates to the concentration of

compounds having a specific degree of ester substitution. Thus, applicants respectfully submit that it is not proper for the Examiner to read the Kaneko patent as teaching a composition in accordance with the present invention simply based upon the reference in that patent to compositions having an HLB value of less than 6.0.

In addition to the above, applicants respectfully submit that there is a large degree of uncertainty regarding the particular manner in which the HLB values referred to in the Kaneko patent would have been determined. As previously explained to the Examiner by way the first Declaration of inventor Durrenberger (the executed version will be filed within the next several days), and as confirmed in the attached Second Declaration of Durrenberger, it is not possible to determine from the Kaneko patent the manner in which the HLB values would have been determined. In the absence of a clear description of the manner for determining HLB values, the reference in the patent to these values is of little or no technical value.

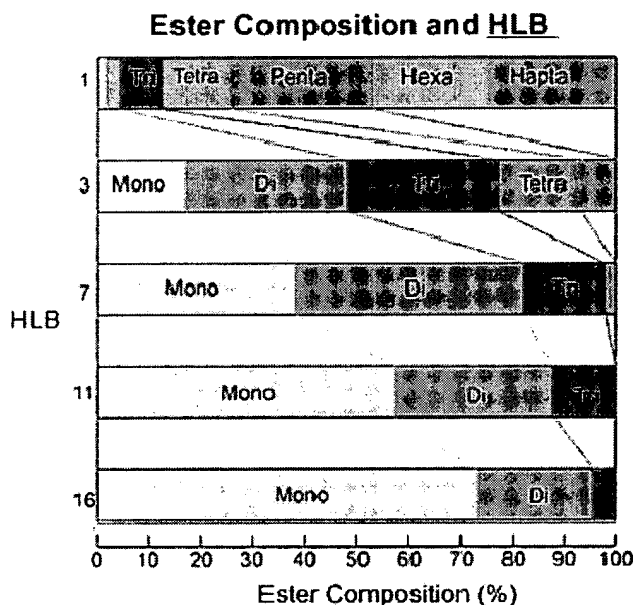
In this regard, the Examiner has suggested during the telephone interview noted above that the claims be amended to include a requirement of a specific HLB value. Applicants have chosen to not follow this suggestion since, among other potential reasons, the reference to HLB values as described in the Kaneko patent is simply not particularly relevant to the requirements of the present claims.

Furthermore, as also previously explained in both of the Durrenberger declarations, the teaching in the Kaneko patent regarding mono- and di-substituted saccharide esters is inconsistent with the notion that a composition comprising at least 50% by weight of fully substituted esters is disclosed. (see First Durrenberger Declaration, paragraph 4). This conclusion is based in part on the fact that this patent actually teaches away from the present invention in that it states that “esters resulting from the complete esterification of organic acid have proven to be ineffective to prevent the shaped body to color in the early stages after molding.” (col. 3. line 73 – col. 4, line 1). As a result, a person skilled in the art at the time the present invention was made would believe that highly substituted esters would not have a heat stabilizing effect on PVC compositions. *Id.* The Kaneko patent, taken as a whole, therefore teaches away from highly substituted esters, included particularly octa-substituted sucrose esters, and instead teaches that mono- and di- substituted sucrose esters should be used. Accordingly, the present claims are not anticipated by Kaneko for at least this reason

Furthermore, even if it were proper to combine the Mitsubishi publication with the Kaneko patent for the purpose of an anticipation rejection (which it is not), this combination would not disclose each and every element of the claim and therefore could not be a proper basis for an anticipation rejection. Mitsubishi discloses mixtures of several sugars. However, it is clear that a composition as required by the present claims can not be achieved by following the teaching of Mitsubishi. The most relevant teaching of Mitsubishi is reproduced below:

### Features of Sugar Esters

- Being tasteless, odorless and nontoxic, they are the best suited emulsifier for foods.
- Being non-irritant to the eyes and skin, they are suitable not only for foods but also for pharmaceuticals and cosmetics.
- Because of their excellent biodegradability they don't cause environmental pollution.
- Sugar Esters offer a full range of **HLB** values from 1 to 16, and in use all grades display exceptionally good surfactant functionality.



As can be seen from the above, the material which has the highest concentration of highly substituted esters is presented in the horizontal bar labeled on the y-axis (HLB) as 1. In this chart, the highest degree of substitution expressly identified is "hapta (sic, hepta)," which represents seven of the possible eight sites being substituted. All other expressly identified compounds have a lower degree of substitution, and according to the chart therefore all of the listed

compositions contain at least about 92% of material that is less than fully substituted. Thus, the Mitsubishi publication **might be** interpreted as disclosing **at most 8% of octa-substituted compound**. This is only a small fraction of the at least 50% of octa-substituted compounds required by the processes of the present claims. It follows, therefore, that the combination of Mitsubishi with Kaneko, even if such combination were proper (which it is not), does not cure Kaneko's lack of disclosure regarding at least 50% octa-ester substituted esters. Accordingly, the present claims are not anticipated by the combination of Kaneko with Mitsubishi for at least this rationale.

**C) Application of *In re Casey* and *In re Otto* is Inopposite**

Applicants note that the Examiner once again incorrectly cites *In re Casey* and *In re Otto* in rejecting claims 2 to 14; the Examiner asserts that the "intended use" allegedly recited in such claims does not "patentably distinguish the claimed invention from the prior art" as such intended use does not "result in a structural difference between the claimed invention and the prior art". (Action, p. 3).

Applicants note that the MPEP expressly states that *In re Casey* and *In re Otto* are "limited to claims directed to machinery which works upon an article or material in its intended use". MPEP § 2115. The present process claims are clearly not directed to machinery. Further, even if the holdings of such cases were applicable (which they are not), claims 2 to 14 define the amount of saccharide ester present in the composition by the effect that such ester has on the composition produced, not on any "intended use" of the composition itself.

Accordingly, the application of *In re Casey* and *In re Otto* to the present claims is inopposite, and certainly does not support the Examiner's rejection.

**E) The Pending Claims are Patentably Non-obvious in view of Kaneko or the Combination of Kaneko and Mitsubishi**

The present rejections based upon obviousness are respectfully traversed.<sup>1</sup>

As noted above, Kaneko and Mitsubishi do not disclose the use of octa-ester substituted sugars in accordance with the present claims. Kaneko itself does not contain any suggestion or motivation to modify the composition disclosed therein or to combine same with any other reference to produce the instantly claimed process; in fact, Kaneko teaches away from the use of octa-ester substituted sugars in an extrusion process by exemplifying and claiming only mono and di-ester substituted sugars.

Mitsubishi also does not contain any suggestion or motivation to combine same with Kaneko to produce the instantly claimed process. **Mitsubishi discloses sugar mixtures which can have at most about 8% of octa-substituted sugars.** Thus, even if Mitsubishi were prior art, its disclosure (either alone or in combination with Kaneko) does not suggest the use in an extrusion process of compositions using sugar mixtures containing at least 50% octa-ester substituted sugars.

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<sup>1</sup> Applicants do not concede that Mitsubishi is prior art to the present invention, but nevertheless, the present invention is shown herein to distinguish patentably over same.

Applicants have discovered, as described extensively in the present specification, that the degree of ester substitution can have an important impact on the properties of the processes which use such a composition. In fact, as demonstrated below with reference to the Declaration of one of the co-inventors, Fred Durrenberger<sup>2</sup>, the use of such a high percentage of octa-substituted saccharide esters produces results which are dramatically and unexpectedly superior to the results achieved with a saccharide esters which have less than such a concentration and are more analogous to those described in the Kaneko patent.

Applicants have unexpectedly found that desirable properties and other unexpected advantages can be achieved by use of saccharide esters in accordance with the claims as now presented. By way of example, but not necessarily by way of limitation, compositions in accordance with the present invention produce superior results in connection with the stability time of such compositions. This finding is demonstrated by experimental data reported in the First Durrenberger Declaration. In addition, applicants present herewith further test results which demonstrate the superior performance of compositions in accordance with the extrusion methods of the present invention. More particularly, as demonstrated and explained in the Second Durrenberger Declaration, Mr. Durrenberger tested and/or supervised the testing of a composition believed to be representative of the material of the type described in

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<sup>2</sup> The undersigned notes that previously an unsigned declaration was filed. The signed copy is filed concurrently with this submission.

the first row of the Mitsubishi publication (HLB =1). The material was obtained from Mitsubishi under the Mitsubishi trade designation "SS 170." The results of testing on this material is presented in the Table below as Sample S 170. The first composition (Sample 1) was made in accordance with the methods as now claimed in the present application.<sup>3</sup> The results of these tests are reported in Table 1 below.

Table 1

Parameter	Test Sample A	Test Sample S 170
Estimated HLB	<<1	1
Degree of Substitution	At least 70 wt.% Octa	Estimated approximately 10% octa-substituted, 90% of substitution hepta or lower
Equilibrium Temp (oC)	212	215
Fusion Torque (mg)	3,370	3500
Equilibrium Torque (mg)	1,860	1904
Fusion Time (min)	47.5	42
Dynamic Stability time, min.*	13.28	9:33

\*elapsed time between fusion and measurable onset of cross-linking

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The results of this test work illustrate one of the important benefits of applicants' invention. More particularly, among other benefits, applicants have discovered that the degree of substitution of the saccharide ester in accordance with the present invention has a significant beneficial effect on the processing characteristics of the shapeable composition and therefore on the present extrusion methods. By way of example, and as mentioned above, the dynamic stability of a shapeable composition can be an important measure of the ability of the composition to undergo processing without disadvantageous degradation and cross-linking. As reported in the above table, the compositions in accordance with the present invention demonstrate a dramatically superior dynamic stability value compared to Sample S 170.<sup>4</sup> More specifically, the compositions of the present invention demonstrate a dynamic heat stability performance (13:28 min) which is **42 relative percent** greater than the dynamic heat stability performance of sample S 170 (9:33 min). Applicants respectfully submit that this is a dramatic and highly desirable result, and furthermore that this result is not in any way suggested or contemplated by the prior art. In fact, if the prior art is relevant at all, it tends to teach away from such a result being possible.

## **CONCLUSION**

In view of the foregoing remarks, applicants assert that the present claims are in condition for allowance and request that the Office issue a Notice of Allowance at the earliest possible date.

The Office is invited to contact Applicants' undersigned counsel by

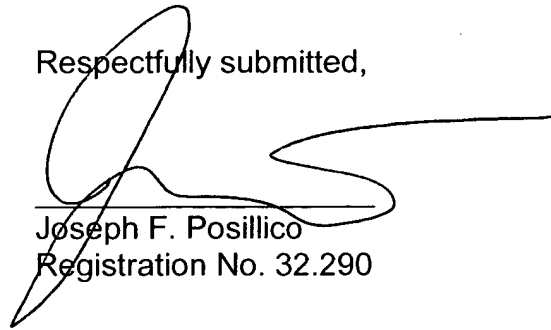
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<sup>4</sup> Applicants do not concede that a material in accordance with Sample 170 is actually prior art to the present invention. Nevertheless, for the purposes of comparison, even such a composition, which may be closer to the present invention than any actual item of prior art, does not demonstrate the advantageous and desirable properties of the present invention.

telephone in order to further the prosecution of this case in any way.

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Respectfully submitted,



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